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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,709	06/08/2007	Koichi Shudo	P28752	9187

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
04/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,709	SHUDO ET AL.	
	Examiner	Art Unit	
	UMA RAMACHANDRAN	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,6-9 and 16-19* is/are pending in the application.

4a) Of the above claim(s) *6 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,7-9,16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/13/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The office acknowledges the receipt of Applicants' response to the office action dated 5/13/2010. Claims 1, 3-5, 10-15 have been cancelled. Claims 2 and 7 have been amended. Claims 6 and 17 have been withdrawn from consideration. Claims 2, 6-9, 16-19 are pending. Claims 2, 7-9, 16, 18 and 19 are examined based on the merits herein.

Response to Remarks

Applicants' amendments necessitated the withdrawal of 112(1) and 112(2) rejection. Applicants' arguments regarding the 103(a) rejections have been fully considered and found not to be persuasive. Applicants' arguments are addressed in the Response to Arguments section below. Applicants' amendments necessitated the modified rejections presented in this office action. Accordingly, the action is made final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

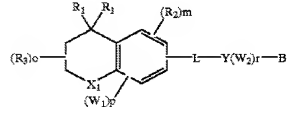
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 7- 9, 16, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (Applicant cited IDS: U.S. 5,965,606) and Goodman (Applicant cited IDS: PNAS, 2003, 100, 5, 2901-05) and Etchamendy (Applicant cited IDS: J Neurosci, 2001, Aug 21(16) p 6423-29).

The prior art Teng et al. teaches retinoid compounds which act specifically or selectively on RAR receptor subtypes and further teaches that the retinoid compounds are useful in treating neurodegenerative conditions like Alzheimer's disease, Parkinson's disease and stroke (See Abstract, col. 1, lines 55-56). The reference states that retinoids are useful for treating animals of the mammalian species including humans. Teng et al. teaches the compounds of formula I:



When X1=[C(R1)2]n, when R1=CH3, n=1, then X1= $-C(CH_3)_2$

R1=CH3

R3= no substituent, o=0

W1=no substituent when p = 0

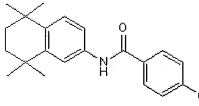
R2= no substituent when m=0

L= -NH-(CO)- when z=O

Y=phenyl

W2= no substituent when r=0

B=-COOH, then the prior art teaches the following compound



(AM80, elected species).

The reference teaches the compounds as retinoid compounds.

Goodman teaches that the late onset Alzheimer's disease is influenced by the availability in brain of retinoic acid (see abstract). It is known in the art that memory fixation disorders are main symptoms of Alzheimer's disease.

Etchamendy teaches that Vitamin A and its derivatives, the retinoids have been implicated recently in the synaptic plasticity of the hippocampus and might therefore play a role in associated cognitive functions (see abstract).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a non-natural retinoid in a therapeutically effective amount to promote formation of long-term memory from short-term memory because of the prior art teachings. Teng et al. teaches compounds with an aromatic ring bound with an aromatic carboxylic acid including the elected species claimed as retinoid compounds. The reference further states that the retinoid compounds are useful in treating neurodegenerative diseases like Alzheimer's disease, Parkinson's disease etc. The limitation "formation of long-term memory from short-term memory" in claim 7 is the preamble and administration of same compound to the same set of patients, for example patients with Alzheimer's disease will have the same therapeutic effects as claimed. See *Ex parte Novitski,* 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The

Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to *Dart* disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating). The teachings of Goodman and Etchamendy teach that retinoids can be useful in Alzheimer's disease and in improvement of cognitive functions. A person of ordinary skill in the art would have found it obvious to try a non natural retinoid compound such as 4-[(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)carbamoyl]benzoic acid (Am80) in promoting memory consolidation because, the compound is known in the art, easily available and known as a retinoid. A person of ordinary skill in the art would have been motivated to use Am80 in Alzheimer's patients to improve the memory impairment. Alzheimer's disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills and memory impairment is associated with Parkinson's disease. A person of ordinary skill in the art would have elected to use the compounds of Teng et al, non natural retinoids in memory consolidation associated with Alzheimer's or Parkinson's disease because memory deficit and memory impairment is associated with both the diseases.

Response to Arguments

Applicants argue that Teng broadly discloses a generic formula that encompasses Am80, it does not provide explicit disclosure of Am80 and Teng broadly discloses many uses for retinoic acid, but does not provide guidance for arriving at Applicants' claimed subject matter. In response to Applicant' arguments, it is argued that Teng broadly discloses the retinoid compounds including Am-80. Also, Teng teaches the retinoid compounds are useful in treating neurodegenerative conditions like Alzheimer's disease, Parkinson's disease and stroke. The limitation introduced in claim 7 is the preamble and administration of same compound to the same set of patients, for example patients with Alzheimer's disease will have the same therapeutic effects as claimed. See *Ex parte Novitski,* 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to *Dart* disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating). An ordinary artisan would have found it obvious from the teachings of Teng that retinoids are useful in treating neurodegenerative diseases including Alzheimer's disease. Am-80 has been well known in the art as a retinoid prior to filing of the application as Applicants have referred to Hashimoto, Y., Cell Struct. Funct., 16, pp.113-123, 1991; Hashimoto, Y., et al.,

Biochem. Biophys. Res. Commun., 166, pp. 1300-1307, 1990) in p 6, lines 26-29 of the specification. Am80 is known in the art, easily available and known as a retinoid. Hence it would have been obvious to a person of ordinary skill in the art to try using Am-80 in treating a neurodegenerative disease such as Alzheimer's disease and administration of Am-80 to an Alzheimer's patient would have had the same therapeutic benefits of promoting formation of long-term memory from short-term memory.

Applicants' argue that Teng does not provide any teaching or suggestion for arriving at a method for promoting formation of long-term memory from short-term memory, comprising administering to a mammal, in need of consolidation of short-term as long-term memory, a therapeutically effective amount of a composition to promote memory consolidation of short- term memory as long-term memory, the composition comprising 4-[(5,6,7,8-tetrahydro-5,5,8,8- tetramethyl-2-naphthalenyl)carbamoyl] benzoic acid as an active ingredient. In response, as stated above, the limitation "promoting formation of long-term memory from short-term memory" is the preamble and administration of a retinoid compound such as Am-80 to the same set of populations say Alzheimer's patient will inherently act the same way whether it is memory consolidation or promoting formation of long-term memory from short-term memory. Teng teaches retinoid compounds including Am-80 as a species to treat neurodegenerative diseases. Accordingly a person of ordinary skill in the art would have found it obvious to use Am-80 in treating neurodegenerative diseases such as Alzheimer's disease and administration of Am-80 would inherently have the same effects of formation of long-term memory from short term memory as claimed.

Applicants' argue that Etchamendy may suggest suppression of reduction of already consolidated long-term memory by retinoic acid, but does not teach or suggest any action of retinoic acid on the consolidation process of short-term to long-term memory. Also it was argued by the Applicants that Goodman does not overcome the deficiencies of either Teng or Etchamendy or any combination thereof. In response, Goodman and Etchamendy have not been added to cure the deficiency of Teng but to add more support to Teng's teachings of why it would have been obvious to a person of ordinary skill in the art at the time of the invention to have used a retinoic acid in treating memory disorders or cognitive disorders.

Conclusion

No claims are allowed.

Applicant's amendment necessitated modified rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMA RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627